K073404

14.0 510(K) SUMMARY

APR 25 2008

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED:

a. Applicant:

IntraLase Corp.
9701 Jeronimo Road
Irvine, CA 92618
Tel: 949.859.5230

b. Contact Person:

Maureen Weiner, R.N.
Regulatory Affairs Consultant
5 Grindlay Pl
Aliso Viejo, CA 92656
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c. Date of Summary Preparation: December 3, 2007

NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME:

Trade/Proprietary Name:	iFS Laser System
Common/Usual Name:	Laser
Classification Name:	Keratome
Classification Code(s):	79 GEX, 86 HNO

IDENTIFICATION OF THE PREDICATE DEVICE OR LEGALLY MARKETED DEVICE OR DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS BEING CLAIMED:

510(k) #	Trade Name	Manufacturer
K060372	IntraLase FS Laser	IntraLase Corp.
K063682	IntraLase Fusion Laser	IntraLase Corp.
K032910	Carriazo Pendular Microkeratome	Schwind Eye Tech Solutions

A DESCRIPTION OF THE DEVICE THAT IS THE SUBJECT OF THE 510(K), INCLUDING EXPLANATION OF HOW THE DEVICE FUNCTIONS, BASIC SCIENTIFIC CONCEPTS, SIGNIFICANT PHYSICAL AND PERFORMANCE CHARACTERISTICS (DESIGN, MATERIAL, PHYSICAL PROPERTIES):

The iFS Laser System is a precision ophthalmic surgical laser designed for use as an ophthalmic surgical laser indicated for use:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments;
- In lamellar keratoplasty and corneal harvesting;
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty.

Corneal dissection with the iFS Laser is achieved through precise individual micro-photodisruptions of tissue, created by tightly focused ultrashort optical which are delivered through a disposable applanation lens assembly while fixating the eye under low vacuum.

STATEMENT OF INTENDED USE:

The iFS Laser System is an ophthalmic surgical laser indicated for use:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea;
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments;
- In lamellar keratoplasty and corneal harvesting;
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty.

STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE:

The technological characteristics of the iFS Laser are substantially equivalent to those cleared under K060372, K063682, and K032910 for corneal resections and incisions.

BRIEF SUMMARY OF NONCLINICAL TESTS AND RESULTS:

The iFS Laser System has undergone testing and is in compliance with applicable safety standards. The iFS Laser and the accessory IntraLase Patient Interface were found to perform equivalently to the predicate laser and patient interface for the creation of corneal resections. Thus, the iFS Laser System and the predicate device have similar safety, effectiveness and performance profiles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2011

Intralase Corporation
c/o Maureen Weiner, R.N.
5 Grindlay Pl.
Aliso Viejo, CA 92656
USA

Re: K073404
Trade/Device Name: iFS Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: II
Product Code: GEX, HNO
Dated: April 8, 2008
Received: April 10, 2008

Dear Ms. Weiner:

This letter corrects our substantially equivalent letter of April 25, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keoia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K073404

Device Name(s): iFS Laser System

Indications for Use:

The iFS Laser System is an ophthalmic surgical laser indicated for use:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments
- In lamellar keratoplasty and corneal harvesting
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty and in the creation of a penetrating cut/incision for penetrating keratoplasty

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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